AF

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/772,134	01/29/2001	David A. Lightfoot	1268/4/2	9557

25297 7590 02/09/2006

JENKINS, WILSON & TAYLOR, P. A.
3100 TOWER BLVD
SUITE 1200
DURHAM, NC 27707

EXAMINER	
KRUSE, DAVID H	

ART UNIT	PAPER NUMBER
1638	

DATE MAILED: 02/09/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/772,134	LIGHTFOOT ET AL.	
	Examiner	Art Unit	
	David H. Kruse	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 November 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *11,13-15,17-26 and 71-81* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *11,13-15,17-26 and 71-81* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *11/09/2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

STATUS OF THE APPLICATION

1. This Office action is in response to the Amendment and Remarks filed on 9 November 2005.

2. The objections to claims 22 and 79 are with drawn in view of Applicant's amendments.

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 101

4. Claims 11, 13-15, 17-26 and 71-81 remain rejected under 35 U.S.C. § 101 because the claimed invention is not supported by either a substantial asserted utility or a well-established utility. This rejection is repeated for the reason of record as set forth in the last Office action mailed 9 May 2004. Applicant's arguments filed 9 November 2005 have been fully considered but they are not persuasive.

Applicants argue that the Patent Office has not provided evidence or sound scientific reasoning to rebut the assertion in the present specification that currently claimed nucleic acids encode functional polypeptides, nor is the Patent Office's decision supported by a preponderance of the evidence (page 9, last paragraph of the Remarks). Applicants argue that positional cloning methods were used to isolate genomic sequences in the chromosomal regions of Forrest that confers SCN/SDS resistance, as further described in Example 4 in the subject U.S. patent application as filed, specifically, rhgl sequences were derived from BAC clones 21D9 and 73P6 of the Forrest BamH or HindIII BAC libraries. Applicants argue that the gene comprises the

nucleotide sequence set forth as SEQ ID NO:13 (Figure 7A-7B of the subject U.S. patent application as filed), and that BLASTP analysis of the translation of the rhgl gene (Figure 7C of the subject U.S. patent application as filed), set forth as SEQ ID:14 shows high homology to GENBANK® Accession No. T46070 described as hypothetical protein T18N14.120 from Arabidopsis thaliana (Figure 7E-7F of the subject U.S. patent application as filed), homology to the rice Xa21 disease resistance gene encoding a leucine-rich repeat protein, and homology to the tomato CF-2 gene for resistance to Cladosporium fulvus (Figure 7D of the subject U.S. patent application as filed) (page 10, 1st paragraph of the Remarks). These arguments are not found to be persuasive. The nucleic acid of SEQ ID NO: 13, encoding SEQ ID NO: 14 appears to be in incomplete coding sequence. The amino acid sequence of SEQ ID NO: 13 does not contain the N-terminal region and contains at lest 17 undefined amino acids in its sequence. The protein designated T18N14.120 from Arabidopsis thaliana is still considered "hypothetical", and Applicants do not teach any common structure that would lead one of skill in the art to accept Applicants' assumption of function as claimed. See *Brenner v. Manson*, 383 U.S. 519 (1966), which states "The basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility. Unless and until a process is refined and developed to this point--where specific benefit exists in currently available form--there is insufficient justification for permitting an applicant to engross what may prove to be a broad field."

Applicants argue that the instant claims are also directed to isolated and purified nucleic acid molecules encoding a soybean Rhg4 gene, and that the gene is capable of conveying Heterodera glycines-infestation resistance to a non-resistant soybean germplasm, the gene located within a quantitative trait locus mapping to linkage group A2 and mapped by the AFLP markers of SEQ ID NOs:6-12, the gene located along said quantitative trait locus between said markers. Preferably, the gene comprises a nucleotide sequence set forth as any one of SEQ ID NOs:16-19 (page 10, 2nd paragraph of the Remarks). This argument is not found to be persuasive because the claimed nucleic acid has not been isolated, Applicant only teaches a possible method of isolating the claimed nucleic acid.

Applicants argue that when the Patent Office takes into account the nature and the degree of the homology between the claimed polypeptides and known disease resistance polypeptides as required in the Interim Examination Guidelines, it is clear that the assignment of function as recited in the present claims is based on a "reasonable correlation" between the homologies of the various proteins (page 11, 3rd paragraph of the Remarks). This argument is not found to be persuasive for the reasons of record and the reasons given supra.

Applicants argue that SEQ ID NO:13 (Figure 7) teaches the utility of marker assisted selection, and that the underline sequence TTGAGGGAAAAGAT teaches the position of a primer that can be extended to score an SNP (C/A change). Applicants argue that section XVI and Table 3 of the subject U.S. patent application show use of a linked marker for this utility (page 11, 4th paragraph of the Remarks). This argument is

not found to be persuasive because the pending claims are directed to an isolated nucleic acid encoding a biologically active SCN/SDS resistance peptide, not to a marker used in a plant breeding method.

Applicants discuss the teaching of the art submitted in the IDS filed on 9 November 2005 at page 12, 2nd and 3rd paragraphs; page 13, 4th and 5th paragraphs; page 14; and page 15, 1st paragraph of the Remarks. The Examiner has reviewed these references and does not find support for applicants asserted substantial or well-established utility.

Applicants confirm that the encoded protein does not start with ATG, but this is not uncommon in plants. Applicants argue that plant transformation experimentation can be a long process, but length does necessarily make the experimentation undue, a functional gene product would be apparent to one of ordinary skill in the art upon a review of the sequences and techniques disclosed in the instant U.S. patent application (page 12, 4th paragraph of the Remarks). This argument is not found to be persuasive because the encoded protein disclosed in SEQ ID NO: 13 is deficient in more than just the ATG start codon as discussed supra. The issue of undue experimentation is irrelevant to the instant rejection directed to lack of a substantial or well-established utility.

Applicants' arguments at page 13, 2nd and 3rd paragraphs are not found to be persuasive because use of an antibody does not establish function, only presence, and the instant issue of utility of the isolated nucleic acid molecule. The DNA sequences for isolating an RHG4 do not establish a utility for an Rhg4 gene that has not been isolated.

Claim Rejections - 35 USC § 112

5. Claims 11, 13-15, 17-26 and 71-81 remain rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement. Specifically, since the claimed invention is not supported by either a substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to make and use the claimed invention. This rejection is repeated for the reason of record as set forth in the last Office action mailed 9 May 2004. Applicant's arguments filed 9 November 2005 have been fully considered but they are not persuasive.

Applicant's arguments as directed to this rejection on pages 16-20 are substantially the same as those addressed supra under 35 USC 101.

6. Claims 11, 13-15, 17-26 and 71-81 remain rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection is repeated for the reason of record as set forth in the last Office action mailed 9 May 2004. Applicant's arguments filed 9 November 2005 have been fully considered but they are not persuasive.

Applicants' arguments in the paragraph spanning pages 20-21 of the Remarks are not found to be persuasive for the reasons given supra. Specifically, the encoded protein of SEQ ID NO: 13 appears to be incomplete, and does not appear to describe

the nucleic acid as broadly claimed. Applicants' arguments in the paragraph spanning pages 21-22 of the Remarks are not found to be persuasive because Applicants only describe primers that could be used to isolated an Rhg4 gene, but Applicants do not describe the genus of Rhg4 genes of the claims. See *Amgen inc. v Chagai Pharmaceutical co.*, 18 USPQ 2d 1016 (Fed. Cir. 1991), which teaches that the conception of a chemical compound requires the inventor to be able to define the compound so as to distinguish it from other materials, and to describe how to obtain it rather than simply defining it solely by its principle biological property; thus, when an inventor of a gene, which is a chemical compound albeit a complex one, is unable to envision detailed constitution of the gene so as to distinguish it from other materials, as well as a method of obtaining it, the conception is not achieved until a reduction to practice has occurred, and until after the gene has been isolated. See *University of California V. Eli Lilly and Co.*, 43 USPQ2d 1398 (Fed. Cir. 1997), which teaches that the disclosure of a process for obtaining cDNA from a particular organism and the description of the encoded protein fail to provide an adequate written description of the actual cDNA from that organism which would encode the protein from that organism, despite the disclosure of a cDNA encoding that protein from another organism.

Applicants argue that the biomolecule is not described solely by a functional characteristic, but that sequence data for the genes themselves is also included. Applicants argue that between SEQ ID NO: 13, which corresponds to Rhg1 and any one of SEQ ID NOs: 16-19, which correspond to Rhg4, there is over 98% sentence identity, and that Applicants submit that one of ordinary skill in the art would recognize

that there is a disclosed correlation between the function described and the structure of the sequence (page 22, 2nd paragraph of the Remarks). These arguments are not found to be persuasive for the reasons given supra under 35 USC 101, in addition SEQ ID NO: 16-19 do not particularly describe an Rhg4 gene, said sequences contain undefined nucleic acids and could only be used to possible isolate the Rhg4 gene which does not describe said gene for the reasons give supra.

7. Claims 11, 14, 21, 24, 25, 71, 74 and 81 remain rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. This rejection is repeated for the reason of record as set forth in the last Office action mailed 9 May 2004. Applicant's arguments filed 9 November 2005 have been fully considered but they are not persuasive.

Claims 11, 14, 21, 24, 25, 71, 74 and 81 are indefinite because there is nothing in the teachings of the instant application that demonstrates that a single resistance polypeptide can have biological activity against soybean cyst nematode infestation and sudden death syndrome (SCN/SDS). The metes and bounds of this claim are unclear given the teachings of Applicants and the art in general. Applicants argue that the specification as filed, for example, discloses that rhg1 "is capable of conveying Heterodera glycines-infestation resistance or Fusarium solani-infection resistance to a non-resistant soybean germplasm" (see Specification at page 39, line 24, to page 40, line 2). Page 40, line 22, through page 41, line 3, of the instant specification discloses that Rhg4 also has this activity (page 24, 2nd paragraph of the Remarks). This

argument is not found to be persuasive the because Applicants use the limitation of encoding or encodes an SCN/SDS resistance polypeptide, where in the art recognizes that the gene loci for soybean cyst nematode and soybean sudden death syndrome are different and distinct, although typically closely associated within the soybean genome.

The issue of "substantially identical to has been obviated by Applicant's amendments to the claims.

Conclusion

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

9. No claims are allowed.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David H. Kruse, Ph.D. whose telephone number is (571) 272-0799. The examiner can normally be reached on Monday to Friday from 8:00 a.m. to 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached at (571) 272-0975. The fax telephone number for this Group is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group Receptionist whose telephone number is (571) 272-0547.

DAVID H. KRUSE, PH.D.
PRIMARY EXAMINER

David H. Kruse, Ph.D.
6 February 2006

11. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.